Pharmacist Guide for Dispensing ABSORICA LD® (isotretinoin)

ABSORICA LD® (isotretinoin capsules) is indicated for the treatment of severe nodular and/or inflammatory acne, acne conglobata and recalcitrant acne. It belongs to the retinoid class of drugs that presents a high risk of congenital malformation and miscarriage as a result of even short lengths of fetal exposure. See the ABSORICA LD Product Monograph for additional detailed information.

Dispensing information and fulfillment

The pharmacist must ensure that:

- The Informed Consent Form is signed by **all** patients prior to starting therapy with ABSORICA LD. This consent form is designed for use by prescribers to ensure that patients have been counselled on and understand the psychiatric and teratogenic risks associated with isotretinoin, prior to starting treatment. Pharmacists should confirm that the patient has signed the consent form.
- It is strongly recommended that each ABSORICA LD prescription be limited to a one-month supply in order to encourage all patients to return for follow-up to monitor side effects.
- It is mandatory that all females or patients of childbearing potential treated with ABSORICA LD have regular negative monthly pregnancy tests prior to receiving each 30-day ABSORICA LD prescription and an additional test one month after the discontinuation of treatment.
- Ideally, pregnancy testing, issuing a prescription and dispensing of ABSORICA LD should occur on the same day.
- Dispensing of ABSORICA LD must occur within a maximum of 7 days of the prescription.
- **Prescriptions presented after 7 days from the prescription date must not be dispensed. The prescription is considered expired.**
- **Two reliable forms of contraception must be used simultaneously.** This includes female patients not using contraception for reasons of infertility, claiming absence of sexual activity or having amenorrhea unless the patient has undergone hysterectomy, bilateral oophorectomy, or has been medically confirmed to be postmenopausal.

Patient communications of safety-related counselling information

Females or patients of childbearing potential:

- **Remind patients that they must use 2 effective forms of contraception simultaneously without any interruption** for 1 month before therapy, during therapy and for 1 month following discontinuation of therapy.
- **Remind patients treated with ABSORICA LD that they must have** regular monthly pregnancy tests during treatment and 1 month after the discontinuation of treatment. Monthly pregnancy tests must be negative prior to receiving each prescription.
- **Warn the patient they must not get pregnant for at least 1 month before treatment, during treatment and at least 1 month after stopping treatment.**
- **Warn patients they must stop taking ABSORICA LD and contact their doctor immediately if they:**
  - Become pregnant while on treatment
  - Become pregnant during the first month after stopping treatment
  - Miss their period
  - Have sex without using effective birth control

Instruct all patients

- **To never give or share this medicine with others.**
- **To return any unused capsules to their pharmacist** at the end of treatment.
- **NOT to donate blood during therapy and for 1 month after stopping treatment** of ABSORICA LD due to potential fetal risk in a pregnant transfusion recipient.
- **That side effects may be serious and should be reported immediately** to the prescribing physician.

Additional information and adverse event reporting

Please visit **https://www.absoricald.ca**.

For information about birth control or confidential counselling, please contact:

- Sun Pharma at **Med.InfoCanada@sunpharma.com** or call **1-833-388-0532**

To report an adverse event, please contact:

- Sun Pharma at **Med.InfoCanada@sunpharma.com** or call **1-833-388-0532** or
- Canada Vigilance program website at **https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html**.

Please consult the Product Monograph at: **https://sunpharma.com/wp-content/uploads/2025/11/PM-Absorica-LD-May-2025-Master.pdf** for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling **1-844-924-0656**.

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